5. The stent of claim 4, wherein said plurality of peaks and valleys include a plurality of U-shaped members, a plurality of Y-shaped members, and a plurality of W-shaped members, whereby a portion of said Y-shaped members forms said plurality of said connecting elements [some of said U-shaped, Y-shaped, and W-shaped members being interconnected].

REMARKS

The Examiner has indicated a defective oath and declaration by failing to identify the application serial numbers of the applications upon which Applicants are claiming benefit under 35 U.S.C. § 120. A corrected oath and declaration will be provided.

The § 112 Rejections

Claim 3 has been rejected under 35 U.S.C. § 112 for failing to specify distances which have been disclosed for the outwardly projecting edges, nor have any minimum distances been identified. Claim 3 has been amended to eliminate any ambiguity as to what distance or how far the outwardly projecting edges of the stent embed into the vascular wall. As the Examiner has pointed out, differences in the size of the stent, the amount of expansion, the diameter of the vessel, the thickness of the vessel wall, etcetera, would require different distances that the outwardly projecting edges would extend. The Examiner's attention is drawn

to page 10, line 30, of the specification and continuing on to page 11, line 10. In that paragraph, it is clearly explained that the dimensions of the stent and the thickness of the various members making up the serpentine pattern 30 will dictate which of the U-shaped, W-shaped, and Y-shaped members that tip radially outwardly to form a projecting edge 34. It is also indicated that the outwardly projecting edges provide for "a roughened outer wall surface of stent 10 and assist in implanting the stent in the vascular wall by embedding into the vascular wall." As amended, claim 3 is believed to overcome the § 112 rejection and is fully supported by the specification and the drawing figures.

Claims 5-7 have been rejected under 35 U.S.C. § 112 for failing to clearly define the connecting elements. Claim 5 has been amended to define the connecting elements as a portion of the Y-shaped members, as was suggested by the Examiner. As is clear, the tail portion of the Y-shaped member is the connecting element between the cylindrical elements. It is believed that claim 5, as amended, overcomes the § 112 rejection. Further, claims 6 and 7 depend from claim 5 and would also overcome the § 112 rejection for the same reasons.

Rejection Under 35 U.S.C. § 102(e)

Claims 1-4, and 8-22 have been rejected under U.S.C. § 102(e) as being anticipated by Palmaz ('417). It is respectfully

urged that claims 1-4, and 8-22, as amended, are patentably distinguishable over the Palmaz '417 patent.

The Examiner has stated that the Palmaz vascular graft has "a plurality of outwardly projecting edges when said stent is in a fully expanded condition; said stent is smooth when in a non-expanded condition... ." It is Applicants' position that the Palmaz '417 patent discloses a vascular graft that has a smooth outer wall surface both when it is in a non-expanded condition, and after the graft has been expanded radially outwardly. As support for Applicants' position, the Examiner is referred to U.S. Patent No. 4,733,665 (enclosed) to Palmaz (hereinafter "the Palmaz '665 patent"). The Palmaz '417 patent is a continuation-in-part of Serial No. 923,798, which issued as U.S. Patent No. 4,739,762, which was a continuation-in-part of Serial No. 796,009 which issued as the Palmaz '665 patent. Also enclosed for the Examiner's review is reexamination certificate B1 4,733,665 to Palmaz (hereinafer "the Palmaz '665 reexam").

As is clear, the Palmaz '665 patent was reexamined and the claims, specifically apparatus claims 13 and 18, were substantially amended to include a smooth outer wall surface on the graft. The smooth outer wall surface language was added during the reexamination to overcome a prior art rejection to U.S. Patent No. 3,657,744 (enclosed) to Ersek (hereinafter "the Ersek patent"). The Ersek patent discloses a plurality of projections on the outer wall surface of the stent. Palmaz was forced to amend his claims

during the reexamination of the '665 patent to include the smooth outer wall surface language in order to overcome the Ersek reference.

Thus, the present state of the prior art is that the Ersek patent has a plurality of projections on its outer wall surface both prior to and after expansion of the graft or stent. According to the Palmaz '665 reexam, the outer surface of the graft is smooth both before and after expansion.

With respect to Applicants' invention, the outer surface of the stent is smooth prior to expansion, but during expansion the projecting members form on the outer surface such that the outer surface is roughened after expansion. Support for this position is found at page 10, lines 30-36 and page 11, line 1 of the specification. It is believed that Applicants' invention distinguishes over the Ersek and Palmaz '665 reexam and '665 patent since neither reference teaches the formation of outwardly projecting members during the expansion process.

With the foregoing in mind, the relationship between the Palmaz '417 patent and the Palmaz '665 patent and Palmaz '665 reexam will now be discussed. As indicated, the '417 patent is a CIP of an earlier-filed application which was a CIP of the '665 patent. Applicants' counsel has carefully reviewed the '417 patent to determine what additions were made to the specification, drawing figures and claims that are new matter. In making this review, counsel for Applicants did not find any teaching in the

specification or the claims that would support the Examiner's rejection that the Palmaz graft has "outwardly projecting edges when said stent is in a fully expanded condition." Since the graft depicted in the '417 patent is substantially the same as that depicted in the '665 patent and '665 reexam, it is respectfully urged that the graft of the '417 patent has a smooth outer wall surface similar to that of the '665 patent as was argued by Palmaz during reexamination proceedings. The Examiner has suggested that Fig. 10 of the '417 patent appears to show outwardly projecting edges. It is believed that Fig. 10 is nothing more than a draftsman rendition of the expanded stent and that any surface irregularity is the result of that rendition. Such a conclusion by the Examiner as to the teachings of Fig. 10 is not supported by the specification, and is in stark contrast to the arguments made by Palmaz with respect to substantially the same stent configuration that was at issue during the reexamination proceedings.

The Examiner also has indicated that the Palmaz '417 stent "can be expanded a small distance radially outwardly without appreciably shortening." Again, it is respectfully urged that there is no teaching in the '417 patent that would support the rejection. Each of the stents or grafts depicted in Figs. 7-10 will shorten when expanded, even though the connector members 101,102 may not cause shortening. Thus, if the Examiner insists upon reliance of the drawing figures to reject Applicants' claims (as urged with respect to Fig. 10), then it is noted that the

expanded vascular grafts depicted in Fig. 10 are in fact substantially shorter than the non-expanded vascular grafts of Fig. 7. Due to the construction of the Palmaz '417 patent grafts, they must in fact shorten somewhat when expanded, which is in contrast to Applicants' stent, which does not appreciably shorten during expansion.

As further support for Applicants' position with respect to shortening, the Examiner's attention is drawn to column 6, lines 63-66 of the Palmaz '665 patent. It is clearly explained that the graft will decrease in length upon expansion of the tubular-shaped member. Although reference is made to 1B of the '665 patent, the embodiment of the graft as shown in Figs. 2A and 2B are also generally described as a wire mesh tube (column 7, lines 25-28). Applicants admit that this language was not carried forward from the Palmaz '665 patent to the Palmaz '417 patent, however, since the grafts are substantially the same from one patent to the other, it is reasonable to believe that the expansion characteristics of the grafts in each patent are substantially the same, and that both will shorten upon expansion.

Applicants also wish to clarify what may be a fundamental misconception with respect to their invention. Each of the expandable cylindrical elements 11 of Applicants invention cannot be construed to be an individual stent or graft. For example, if one expandable cylindrical element 11 were mounted on the balloon portion of a catheter, and delivered intraluminally and expanded at

a stenosed area of a coronary artery, the single cylindrical element 11 could not possibly hold open and support the vessel wall after it was expanded. As is repeatedly stated in Applicants' specification, these devices are to be used primarily in the coronary arteries requiring an extremely small size, on the order of approximately 15 to 20mm in length, and perhaps 4mm in diameter when fully expanded. Thus, a single cylindrical element 11 would be incapable of functioning as a stent, as that term is used in the specification and claims of the present application.

Given the foregoing argument, when the Examiner rejects claims 1-4 and 8-22 by saying that the '417 patent teaches "a plurality of parallel connecting elements 100, see Fig. 7," the Examiner is actually referring to a plurality of prostheses or grafts being connected together by connecting elements. As clearly pointed out, Applicants have not connected a plurality of stents together by connecting cylindrical elements. Applicants have formed one stent by connecting a plurality of cylindrical elements together. The cylindrical elements, in and of themselves, are not stents which function for the stated purpose. The Palmaz '417 patent connects a plurality of grafts with connecting elements 100, but it does not teach connecting cylindrical elements together to form one graft.

For all of the foregoing reasons, it is respectfully urged that claims 1-4 and 8-22 are patentably distinguishable over

the Palmaz '417 patent, and it is requested that the Examiner withdraw the § 102(e) rejection.

Rejection Under 35 U.S.C. § 102(b) and § 103

Claim 24 has been rejected under § 102(b) as being anticipated by Palmaz ('337), and claim 23 has been rejected under § 103 as being unpatentable over the prior art admitted by Applicants on page 2 of the specification in view of the Palmaz '417 patent as applied to the claims above. Claims 23 and 24 have been cancelled without prejudice from the application.

* * *

The Examiner has indicated that claims 5-7 would be allowable if rewritten to overcome the rejection under 35 U.S.C. § 112 and to include all of the limitations of the base claim and any intervening claims. Applicants gratefully acknowledge the allowability of the claims, however, in view of the amendments to the claims and the arguments made above, it is believed that claims 5-7 are allowable over the art of record, and have been amended to overcome the § 112 rejection.

Applicants acknowledge that the prior art made of record and not relied upon is considered pertinent to Applicants' disclosure.

It is respectfully urged that all of the pending claims are patentably distinguishable over the art of record, and that all § 112 rejections have been addressed. Accordingly, Applicants believe the claims are in condition for allowance and early consideration is requested.

Again, Applicants' counsel is requesting a personal interview with the Examiner at a mutually convenient time in order to discuss the prior art. It is also requested that the Director of Research for the Assignee and a clinical coordinator of the Assignee be present during any interview. The Assignee of the present application is conducting substantial clinical trials in Europe and the Director of Research and a Clinical Coordinator can describe for the Examiner any details of the present invention which are not readily apparent from the foregoing remarks.

Respectfully submitted,

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